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(54) **METHOD AND SYSTEM FOR PROVIDING ANALYTE MONITORING**

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This patent is subject to a terminal disclaimer.

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CPC ***A61B 5/14532*** (2013.01); ***A61B 5/002*** (2013.01); ***A61B 5/1473*** (2013.01); ***A61B 5/1486*** (2013.01); ***A61B 5/14503*** (2013.01); ***A61B 5/14546*** (2013.01); ***G06Q 50/24*** (2013.01); *A61B 5/1468* (2013.01); *G06F 19/3406* (2013.01); *G06F 19/3456* (2013.01)

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See application file for complete search history.

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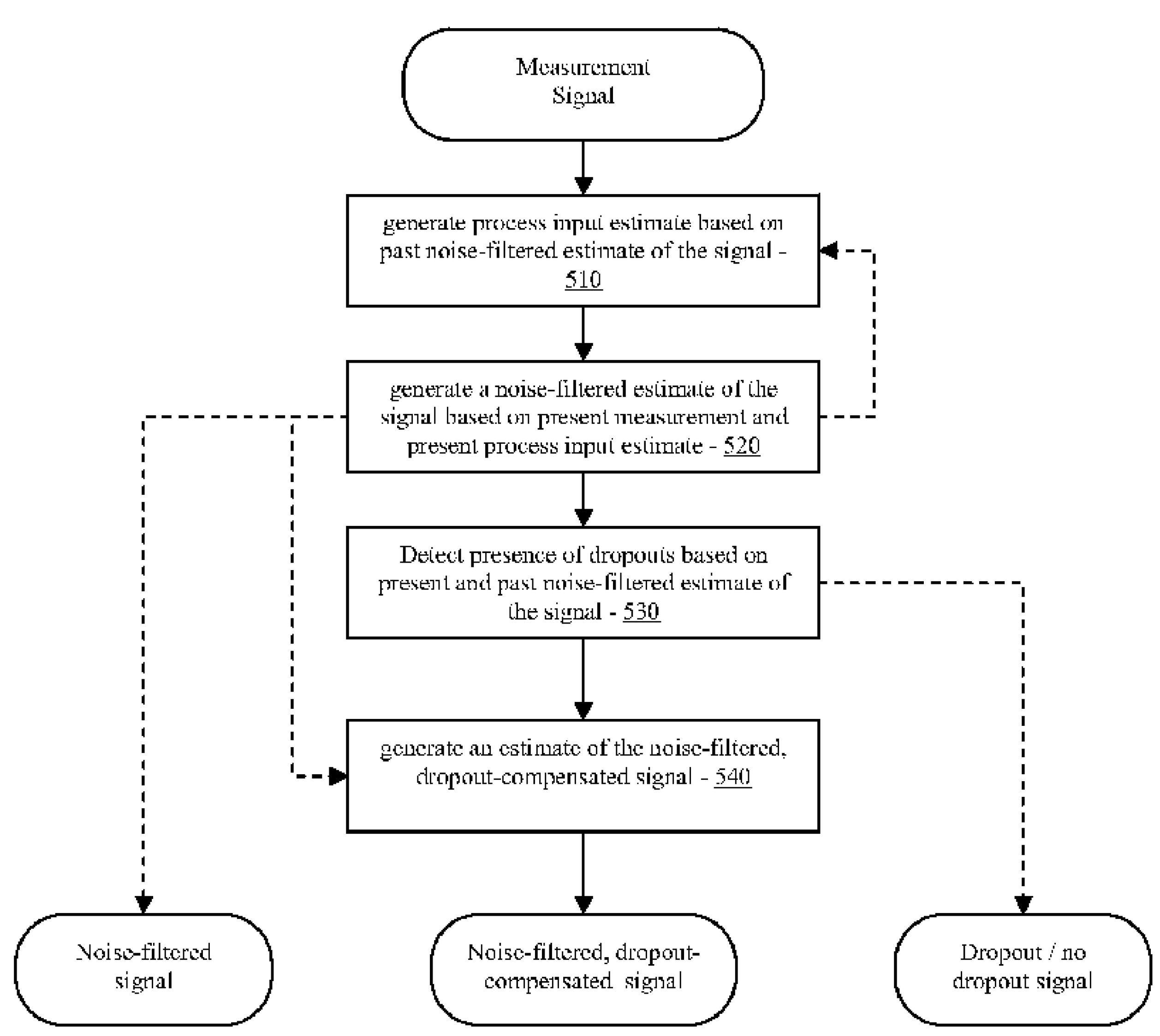
(57) **ABSTRACT**

Methods and apparatuses for determining an analyte value are disclosed.

12 Claims, 9 Drawing Sheets



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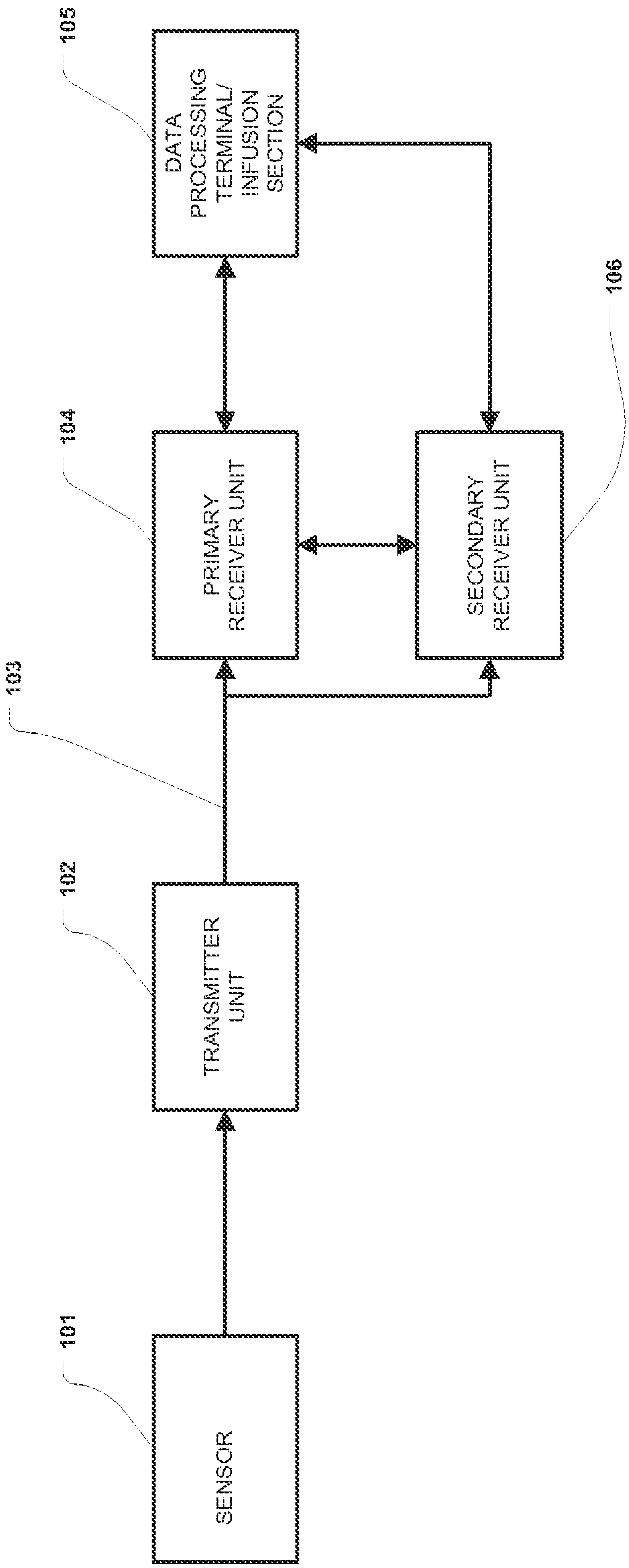
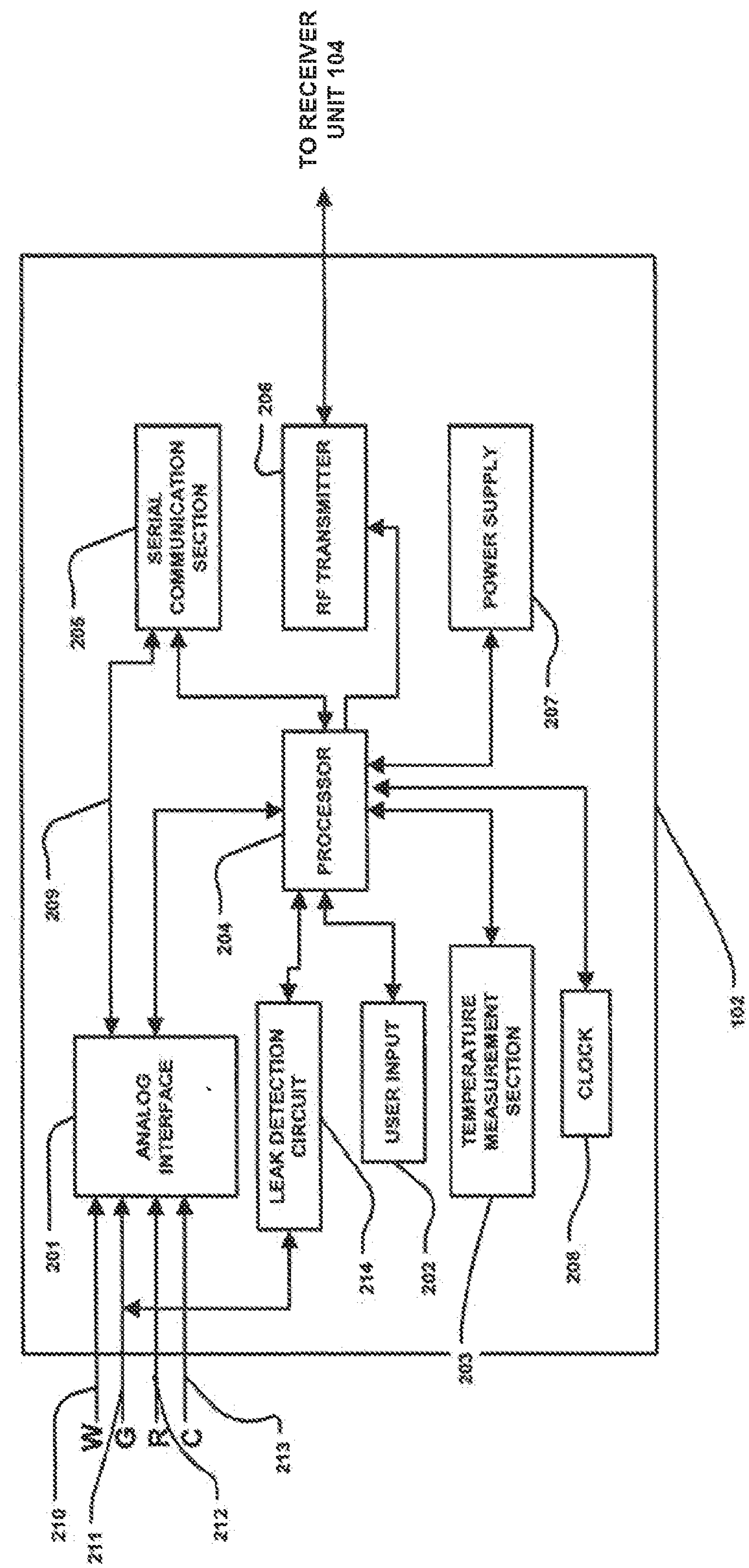

101
SENSOR
102
TRANSMITTER UNIT
103
104
PRIMARY RECEIVER UNIT
105
DATA PROCESSING TERMINAL/ INFUSION SECTION
106
SECONDARY RECEIVER UNIT

100

FIGURE 1


TO RECEIVER UNIT 104
SERIAL COMMUNICATION SECTION
RF TRANSMITTER
POWER SUPPLY
PROCESSOR
ANALOG INTERFACE
LEAK DETECTION CIRCUIT
USER INPUT
TEMPERATURE MEASUREMENT SECTION
CLOCK
W
G
R
C
205
206
207
209
204
201
214
202
203
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102
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211
212
213

FIGURE 2

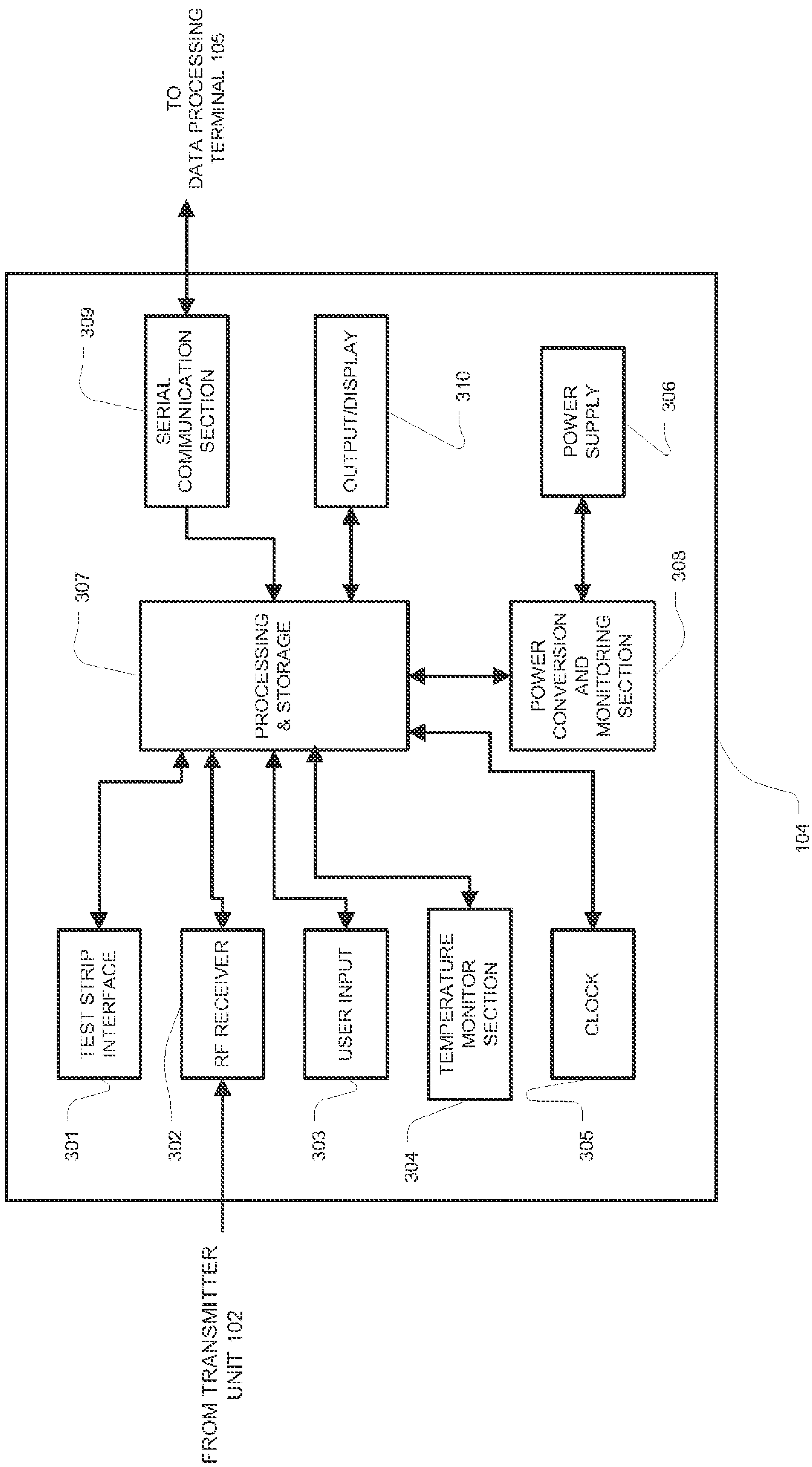
TO
DATA PROCESSING
TERMINAL 105
SERIAL
COMMUNICATION
SECTION
309
OUTPUT/DISPLAY
310
POWER
SUPPLY
306
PROCESSING
& STORAGE
307
POWER
CONVERSION
AND
MONITORING
SECTION
308
TEST STRIP
INTERFACE
301
RF RECEIVER
302
USER INPUT
303
TEMPERATURE
MONITOR
SECTION
304
CLOCK
305
104
FROM TRANSMITTER
UNIT 102

FIGURE 3

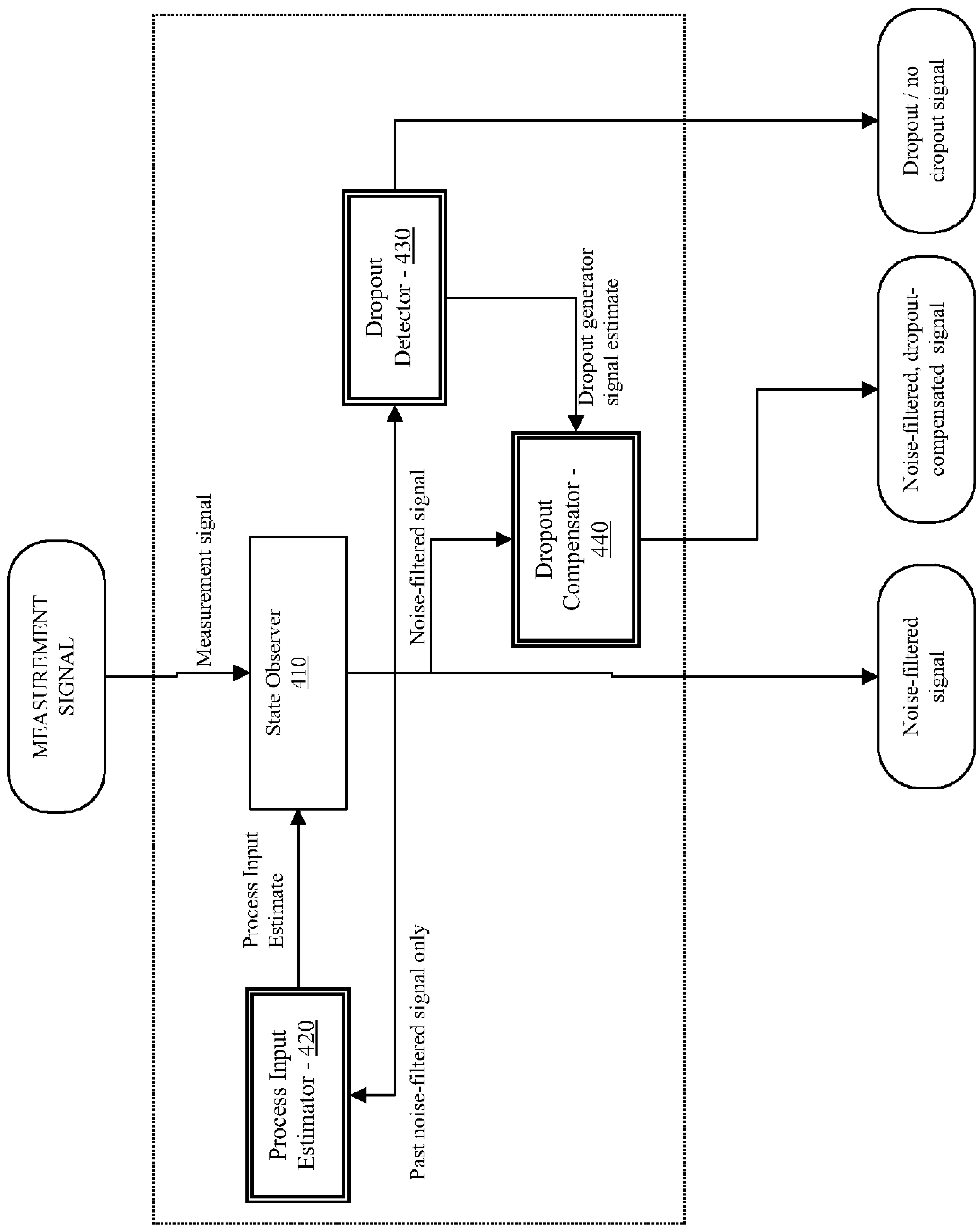
MEASUREMENT SIGNAL
Measurement signal
State Observer 410
Process Input Estimate
Process Input Estimator - 420
Past noise-filtered signal only
Noise-filtered signal
Dropout Detector - 430
Dropout generator signal estimate
Dropout Compensator - 440
Dropout / no dropout signal
Noise-filtered, dropout-compensated signal
Noise-filtered signal

FIGURE 4

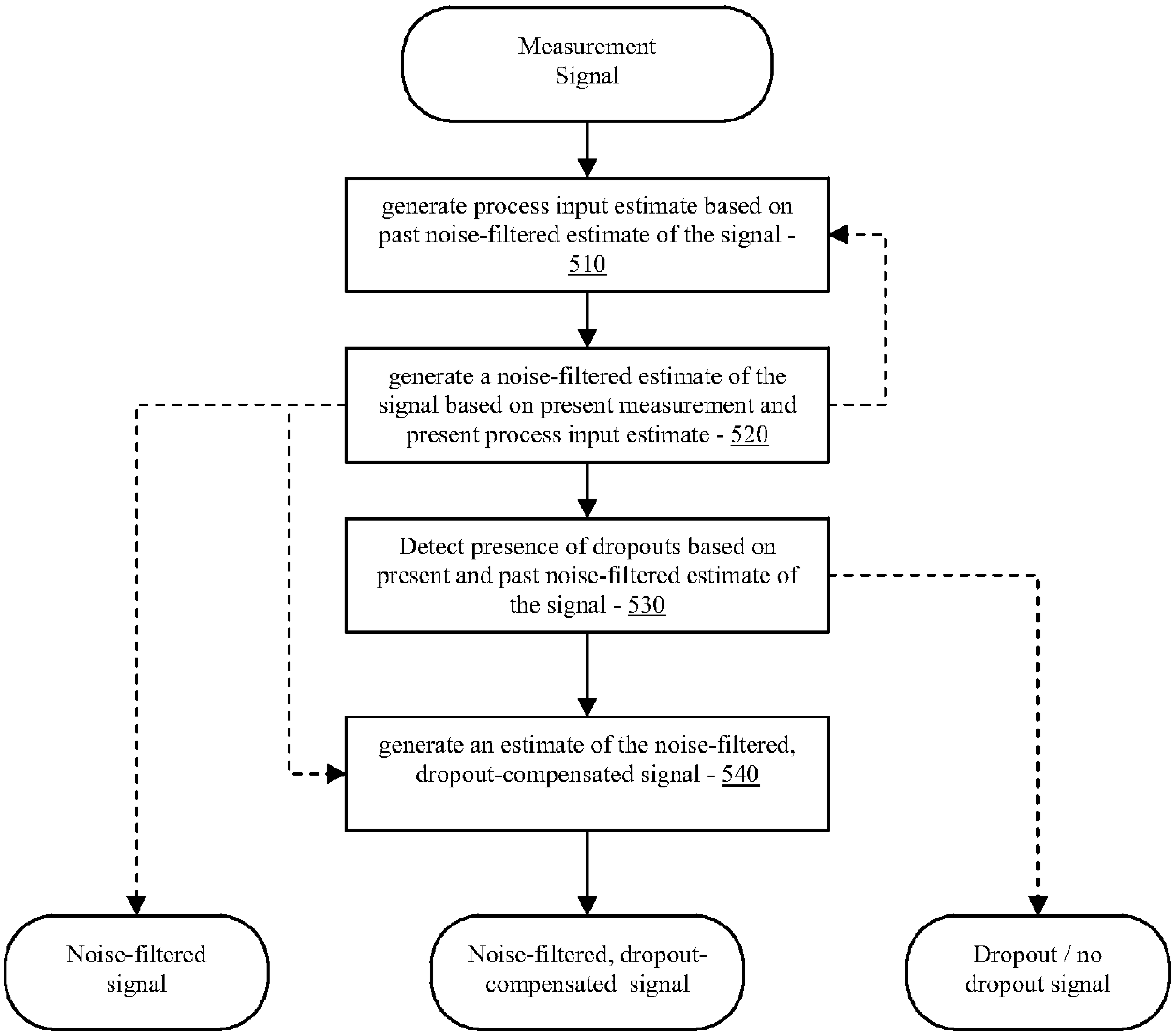
Measurement Signal
generate process input estimate based on past noise-filtered estimate of the signal - 510
generate a noise-filtered estimate of the signal based on present measurement and present process input estimate - 520
Detect presence of dropouts based on present and past noise-filtered estimate of the signal - 530
generate an estimate of the noise-filtered, dropout-compensated signal - 540
Noise-filtered signal
Noise-filtered, dropout-compensated signal
Dropout / no dropout signal

FIGURE 5

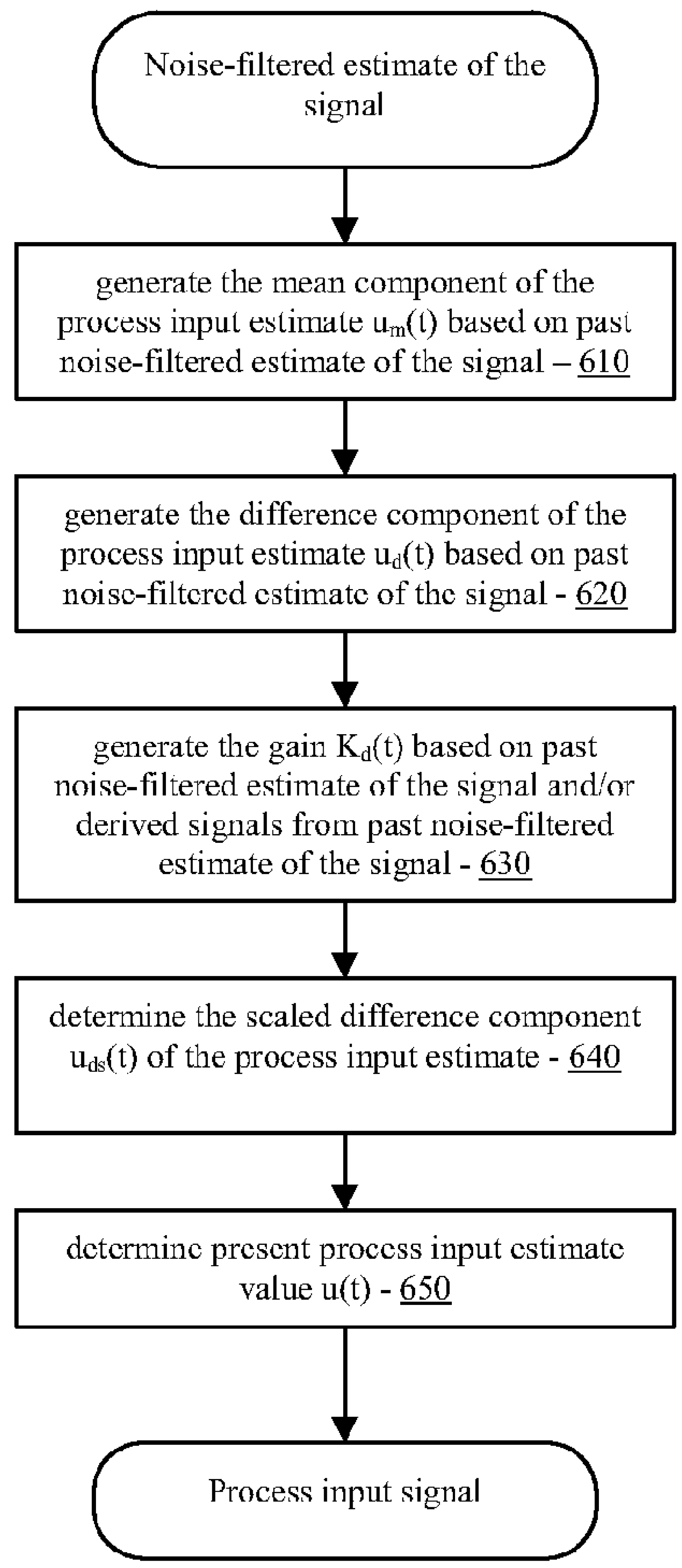

FIGURE 6

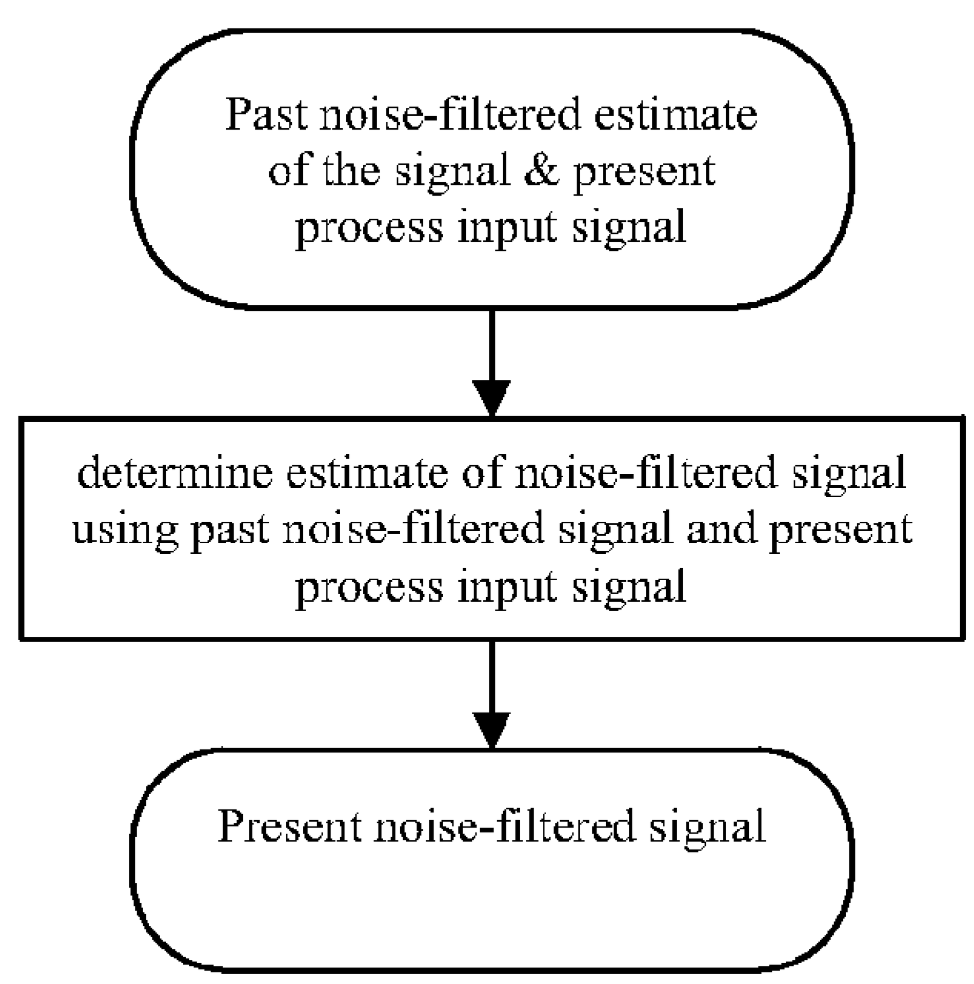

FIGURE 7

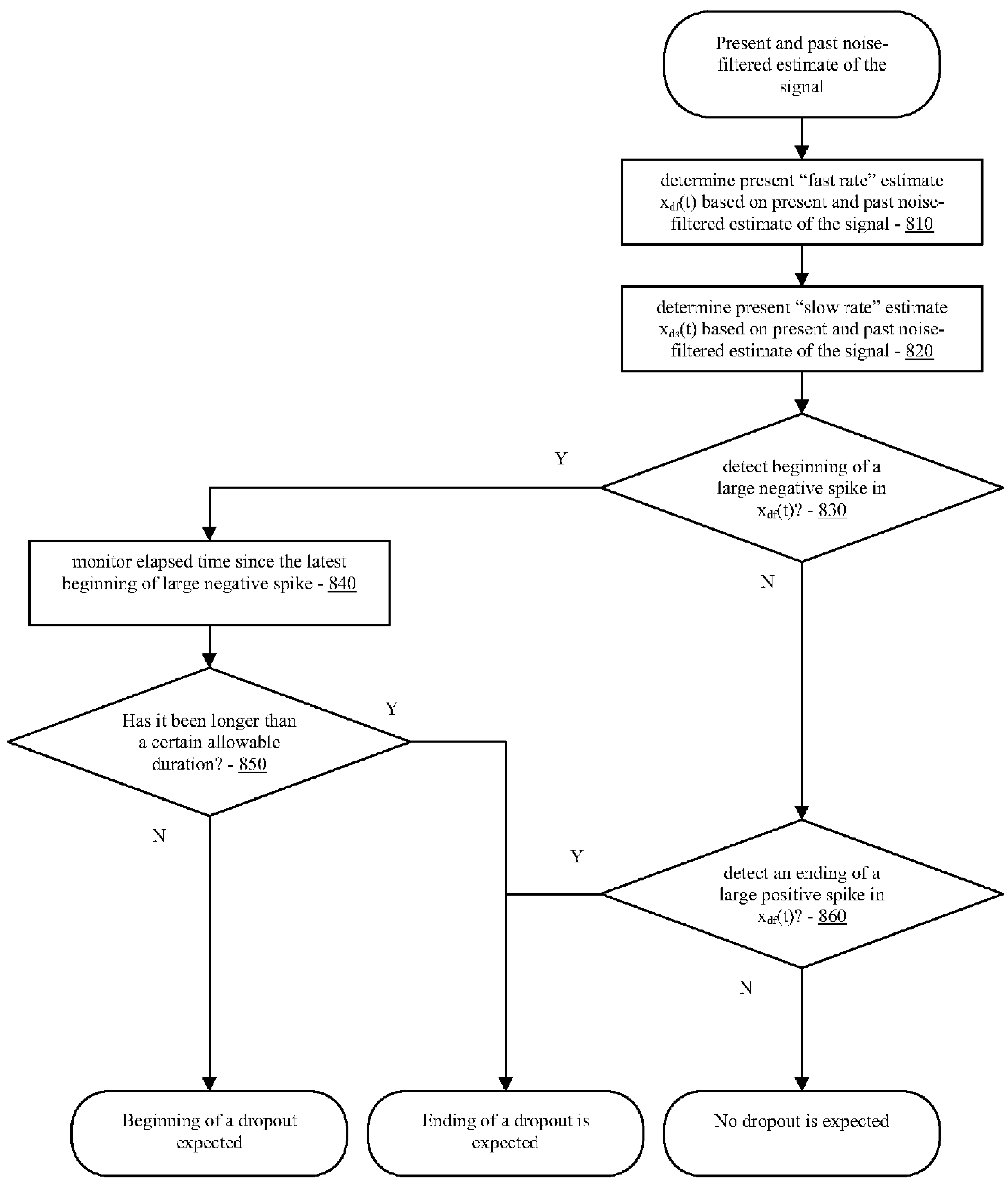
Present and past noise-filtered estimate of the signal
determine present "fast rate" estimate $x_{df}(t)$ based on present and past noise-filtered estimate of the signal - 810
determine present "slow rate" estimate $x_{ds}(t)$ based on present and past noise-filtered estimate of the signal - 820
detect beginning of a large negative spike in $x_{df}(t)$? - 830
Y
N
monitor elapsed time since the latest beginning of large negative spike - 840
Has it been longer than a certain allowable duration? - 850
Y
N
detect an ending of a large positive spike in $x_{df}(t)$? - 860
Y
N
Beginning of a dropout expected
Ending of a dropout is expected
No dropout is expected

FIGURE 8

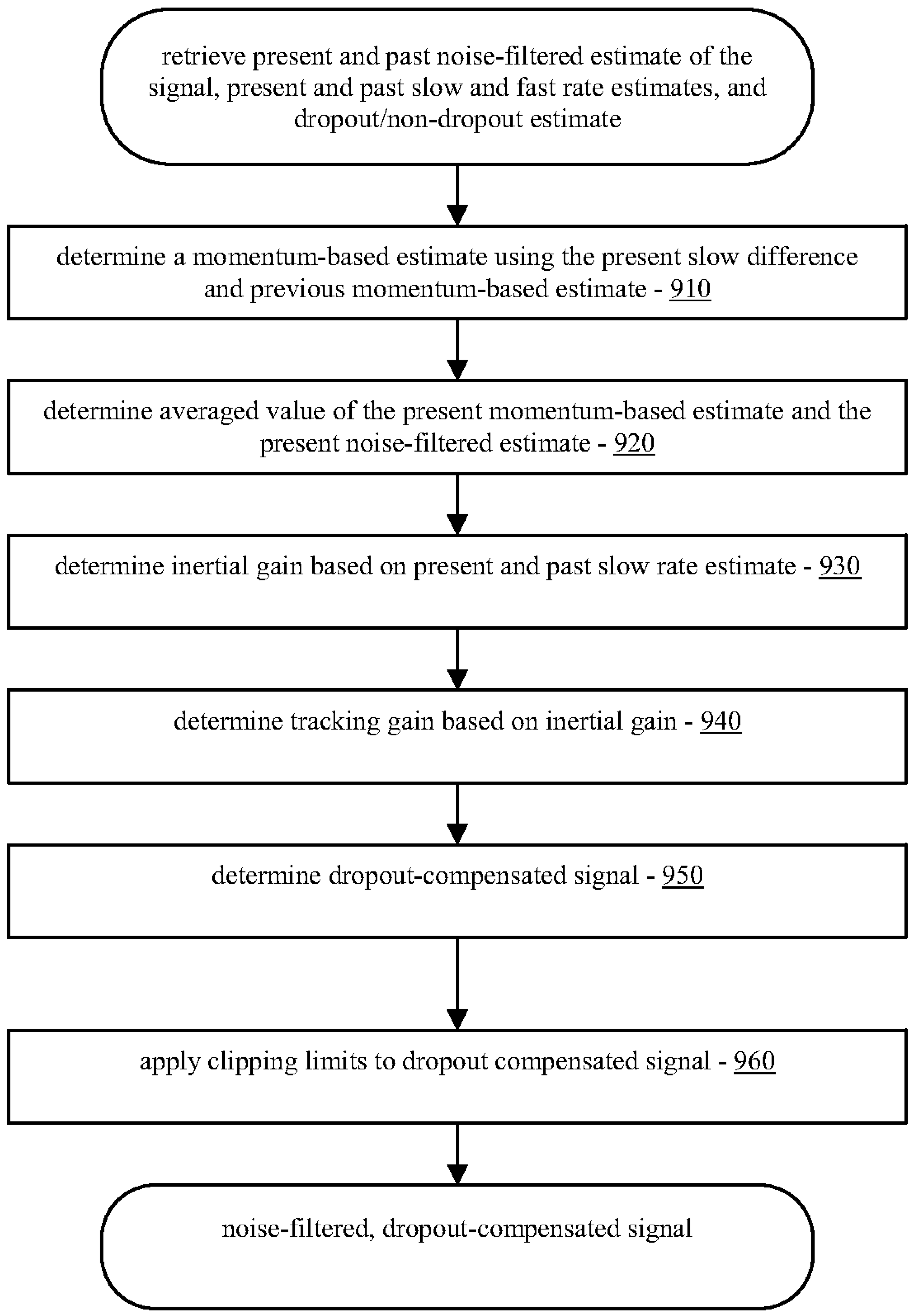
retrieve present and past noise-filtered estimate of the signal, present and past slow and fast rate estimates, and dropout/non-dropout estimate
determine a momentum-based estimate using the present slow difference and previous momentum-based estimate - 910
determine averaged value of the present momentum-based estimate and the present noise-filtered estimate - 920
determine inertial gain based on present and past slow rate estimate - 930
determine tracking gain based on inertial gain - 940
determine dropout-compensated signal - 950
apply clipping limits to dropout compensated signal - 960
noise-filtered, dropout-compensated signal

FIGURE 9

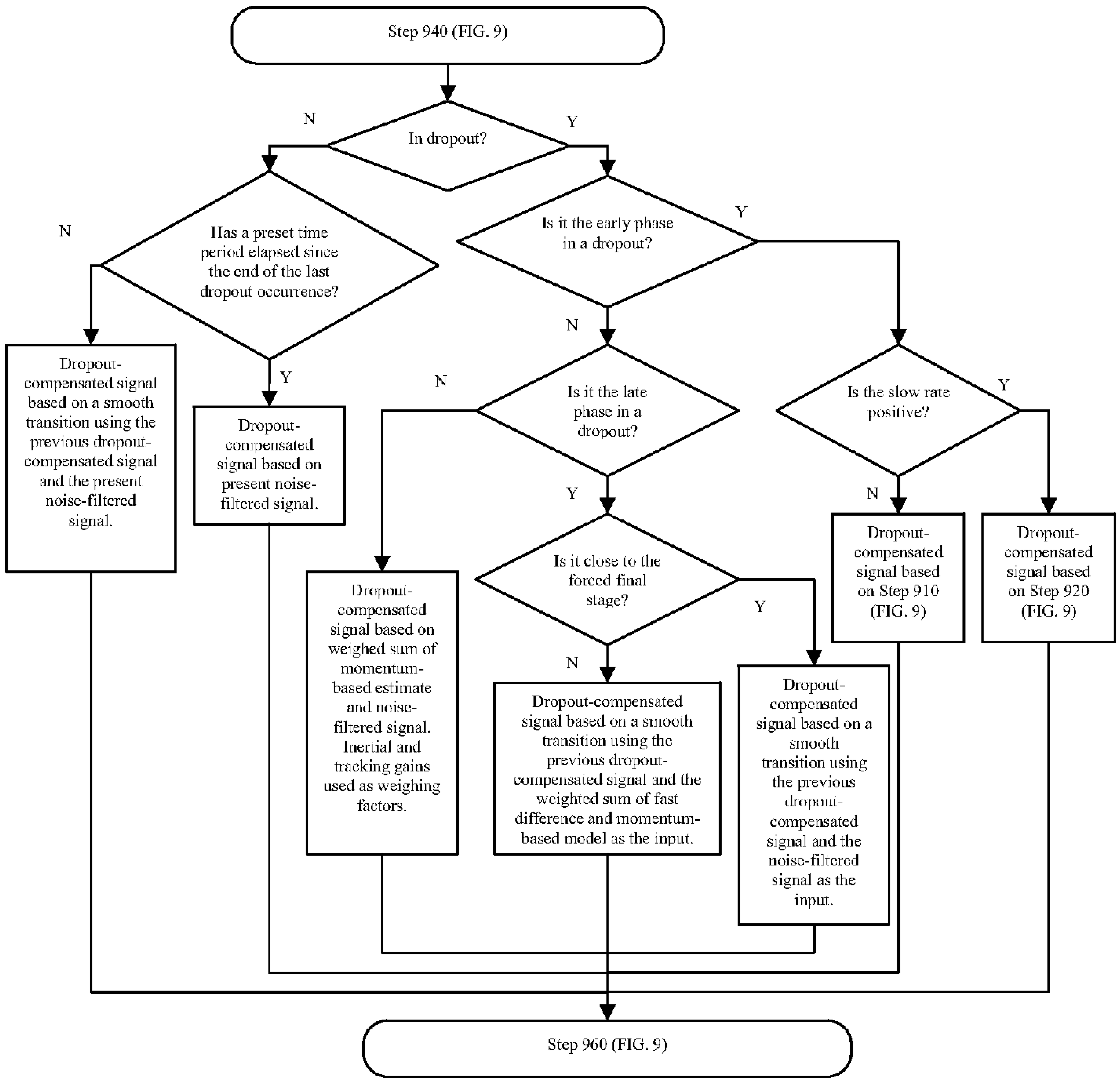
Step 940 (FIG. 9)
In dropout?
N
Y
Has a preset time period elapsed since the end of the last dropout occurrence?
Is it the early phase in a dropout?
Dropout-compensated signal based on a smooth transition using the previous dropout-compensated signal and the present noise-filtered signal.
Dropout-compensated signal based on present noise-filtered signal.
Is it the late phase in a dropout?
Is the slow rate positive?
Is it close to the forced final stage?
Dropout-compensated signal based on Step 910 (FIG. 9)
Dropout-compensated signal based on Step 920 (FIG. 9)
Dropout-compensated signal based on weighed sum of momentum-based estimate and noise-filtered signal. Inertial and tracking gains used as weighing factors.
Dropout-compensated signal based on a smooth transition using the previous dropout-compensated signal and the weighted sum of fast difference and momentum-based model as the input.
Dropout-compensated signal based on a smooth transition using the previous dropout-compensated signal and the noise-filtered signal as the input.
Step 960 (FIG. 9)

FIGURE 10

METHOD AND SYSTEM FOR PROVIDING ANALYTE MONITORING

RELATED APPLICATIONS

The present application is a continuation of U.S. patent application Ser. No. 12/506,227 filed Jul. 20, 2009, now U.S. Pat. No. 8,216,137, which is a continuation of U.S. patent application Ser. No. 11/552,935 filed Oct. 25, 2006, now U.S. Pat. No. 7,630,748, entitled "Method and System for Providing Analyte Monitoring," the disclosures of each of which are incorporated herein by reference for all purposes.

BACKGROUND

Analyte, e.g., glucose monitoring systems including continuous and discrete monitoring systems generally include a small, lightweight battery powered and microprocessor controlled system which is configured to detect signals proportional to the corresponding measured glucose levels using an electrometer, and RF signals to transmit the collected data. One aspect of certain analyte monitoring systems include a transcutaneous or subcutaneous analyte sensor configuration which is, for example, partially mounted on the skin of a subject whose analyte level is to be monitored. The sensor cell may use a two or three-electrode (work, reference and counter electrodes) configuration driven by a controlled potential (potentiostat) analog circuit connected through a contact system.

The analyte sensor may be configured so that a portion thereof is placed under the skin of the patient so as to detect the analyte levels of the patient, and another segment of the analyte sensor that is in communication with the transmitter unit. The transmitter unit is configured to transmit the analyte levels detected by the sensor over a wireless communication link such as an RF (radio frequency) communication link to a receiver/monitor unit. The receiver/monitor unit performs data analysis, among others on the received analyte levels to generate information pertaining to the monitored analyte levels.

To obtain accurate data from the analyte sensor, calibration using capillary blood glucose measurements is necessary. Typically, blood glucose measurements are obtained using, for example, a blood glucose meter, and the measured blood glucose values are used to calibrate the sensors. Due to a lag factor between the monitored sensor data and the measured blood glucose values, an error, or signal noise such as signal dropouts, is typically introduced in calibration using the monitored data as well as in computing the displayed glucose value. While correcting for the lag factors can minimize the error due to lag in the presence of noise, in the presence of signal dropouts, such error compensation may reduce accuracy of the monitored sensor data.

In view of the foregoing, it would be desirable to have a method and system for providing noise filtering and signal dropout detection and/or compensation in data monitoring systems.

SUMMARY OF THE INVENTION

In one embodiment, a method for minimizing the effect of noise and signal dropouts in a glucose sensor including monitoring a data stream, generating a noise-filtered signal associated with the data stream, determining a presence of a signal dropout based on the noise filtered signal, and estimating a noise filtered dropout compensated signal based on the noise filtered signal and the determination of the presence of the signal dropout are disclosed.

These and other objects, features and advantages of the present invention will become more fully apparent from the following detailed description of the embodiments, the appended claims and the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** illustrates a block diagram of a data monitoring and management system for practicing one or more embodiments of the present invention;

FIG. **2** is a block diagram of the transmitter unit of the data monitoring and management system shown in FIG. **1** in accordance with one embodiment of the present invention;

FIG. **3** is a block diagram of the receiver/monitor unit of the data monitoring and management system shown in FIG. **1** in accordance with one embodiment of the present invention;

FIG. **4** is a functional diagram of the overall signal processing for noise filtering and signal dropout compensation in accordance with one embodiment of the present invention;

FIG. **5** is a flowchart illustrating the overall signal processing for noise filtering and signal dropout compensation in accordance with one embodiment of the present invention;

FIG. **6** is a flowchart illustrating the process input estimation in accordance with one embodiment of the present invention;

FIG. **7** is a flowchart illustrating the noise filtered estimation;

FIG. **8** is a flowchart illustrating signal dropout detection in accordance with one embodiment of the present invention;

FIG. **9** is a flowchart illustrating an overall signal dropout compensation in accordance with one embodiment of the present invention; and

FIG. **10** is flowchart illustrating a detailed signal dropout compensation determination of FIG. **9** in accordance with one embodiment of the present invention.

DETAILED DESCRIPTION

As described in further detail below, in accordance with the various embodiments of the present invention, there is provided a method and system for providing noise filtered and/or signal dropout mitigated processes for signals in analyte monitoring systems. In particular, within the scope of the present invention, there are provided method and system for noise filtering, signal dropout detection, and signal dropout compensation to improve the accuracy of lag compensation.

FIG. **1** illustrates a data monitoring and management system such as, for example, analyte (e.g., glucose) monitoring system **100** in accordance with one embodiment of the present invention. The subject invention is further described primarily with respect to a glucose monitoring system for convenience and such description is in no way intended to limit the scope of the invention. It is to be understood that the analyte monitoring system may be configured to monitor a variety of analytes, e.g., lactate, and the like.

Analytes that may be monitored include, for example, acetyl choline, amylase, bilirubin, cholesterol, chorionic gonadotropin, creatine kinase (e.g., CK-MB), creatine, DNA, fructosamine, glucose, glutamine, growth hormones, hormones, ketones, lactate, peroxide, prostate-specific antigen, prothrombin, RNA, thyroid stimulating hormone, and troponin. The concentration of drugs, such as, for example, antibiotics (e.g., gentamicin, vancomycin, and the like), digitoxin, digoxin, drugs of abuse, theophylline, and warfarin, may also be monitored.

The analyte monitoring system **100** includes a sensor **101**, a transmitter unit **102** coupled to the sensor **101**, and a primary receiver unit **104** which is configured to communicate with the transmitter unit **102** via a communication link **103**. The primary receiver unit **104** may be further configured to transmit data to a data processing terminal **105** for evaluating the data received by the primary receiver unit **104**. Moreover, the data processing terminal in one embodiment may be configured to receive data directly from the transmitter unit **102** via a communication link which may optionally be configured for bi-directional communication.

Also shown in FIG. **1** is a secondary receiver unit **106** which is operatively coupled to the communication link and configured to receive data transmitted from the transmitter unit **102**. Moreover, as shown in the Figure, the secondary receiver unit **106** is configured to communicate with the primary receiver unit **104** as well as the data processing terminal **105**. Indeed, the secondary receiver unit **106** may be configured for bi-directional wireless communication with each of the primary receiver unit **104** and the data processing terminal **105**. As discussed in further detail below, in one embodiment of the present invention, the secondary receiver unit **106** may be configured to include a limited number of functions and features as compared with the primary receiver unit **104**. As such, the secondary receiver unit **106** may be configured substantially in a smaller compact housing or embodied in a device such as a wrist watch, for example. Alternatively, the secondary receiver unit **106** may be configured with the same or substantially similar functionality as the primary receiver unit **104**, and may be configured to be used in conjunction with a docking cradle unit for placement by bedside, for night time monitoring, and/or bi-directional communication device.

Only one sensor **101**, transmitter unit **102**, communication link **103**, and data processing terminal **105** are shown in the embodiment of the analyte monitoring system **100** illustrated in FIG. **1**. However, it will be appreciated by one of ordinary skill in the art that the analyte monitoring system **100** may include one or more sensor **101**, transmitter unit **102**, communication link **103**, and data processing terminal **105**. Moreover, within the scope of the present invention, the analyte monitoring system **100** may be a continuous monitoring system, or semi-continuous, or a discrete monitoring system. In a multi-component environment, each device is configured to be uniquely identified by each of the other devices in the system so that communication conflict is readily resolved between the various components within the analyte monitoring system **100**.

In one embodiment of the present invention, the sensor **101** is physically positioned in or on the body of a user whose analyte level is being monitored. The sensor **101** may be configured to continuously sample the analyte level of the user and convert the sampled analyte level into a corresponding data signal for transmission by the transmitter unit **102**. In one embodiment, the transmitter unit **102** is mounted on the sensor **101** so that both devices are positioned on the user's body. The transmitter unit **102** performs data processing such as filtering and encoding on data signals, each of which corresponds to a sampled analyte level of the user, for transmission to the primary receiver unit **104** via the communication link **103**.

In one embodiment, the analyte monitoring system **100** is configured as a one-way RF communication path from the transmitter unit **102** to the primary receiver unit **104**. In such embodiment, the transmitter unit **102** transmits the sampled data signals received from the sensor **101** without acknowledgement from the primary receiver unit **104** that the transmitted sampled data signals have been received. For example, the transmitter unit **102** may be configured to transmit the encoded sampled data signals at a fixed rate (e.g., at one minute intervals) after the completion of the initial power on procedure. Likewise, the primary receiver unit **104** may be configured to detect such transmitted encoded sampled data signals at predetermined time intervals. Alternatively, the analyte monitoring system **100** may be configured with a bi-directional RF (or otherwise) communication between the transmitter unit **102** and the primary receiver unit **104**.

Additionally, in one aspect, the primary receiver unit **104** may include two sections. The first section is an analog interface section that is configured to communicate with the transmitter unit **102** via the communication link **103**. In one embodiment, the analog interface section may include an RF receiver and an antenna for receiving and amplifying the data signals from the transmitter unit **102**, which are thereafter, demodulated with a local oscillator and filtered through a band-pass filter. The second section of the primary receiver unit **104** is a data processing section which is configured to process the data signals received from the transmitter unit **102** such as by performing data decoding, error detection and correction, data clock generation, and data bit recovery.

In operation, upon completing the power-on procedure, the primary receiver unit **104** is configured to detect the presence of the transmitter unit **102** within its range based on, for example, the strength of the detected data signals received from the transmitter unit **102** or a predetermined transmitter identification information. Upon successful synchronization with the corresponding transmitter unit **102**, the primary receiver unit **104** is configured to begin receiving from the transmitter unit **102** data signals corresponding to the user's detected analyte level. More specifically, the primary receiver unit **104** in one embodiment is configured to perform synchronized time hopping with the corresponding synchronized transmitter unit **102** via the communication link **103** to obtain the user's detected analyte level.

Referring again to FIG. **1**, the data processing terminal **105** may include a personal computer, a portable computer such as a laptop or a handheld device (e.g., personal digital assistants (PDAs)), and the like, each of which may be configured for data communication with the receiver via a wired or a wireless connection. Additionally, the data processing terminal **105** may further be connected to a data network (not shown) for storing, retrieving and updating data corresponding to the detected analyte level of the user.

Within the scope of the present invention, the data processing terminal **105** may include an infusion device such as an insulin infusion pump or the like, which may be configured to administer insulin to patients, and which may be configured to communicate with the receiver unit **104** for receiving, among others, the measured analyte level. Alternatively, the receiver unit **104** may be configured to integrate an infusion device therein so that the receiver unit **104** is configured to administer insulin therapy to patients, for example, for administering and modifying basal profiles, as well as for determining appropriate boluses for administration based on, among others, the detected analyte levels received from the transmitter unit **102**.

Additionally, the transmitter unit **102**, the primary receiver unit **104** and the data processing terminal **105** may each be configured for bi-directional wireless communication such that each of the transmitter unit **102**, the primary receiver unit **104** and the data processing terminal **105** may be configured to communicate (that is, transmit data to and receive data from) with each other via the wireless communication link **103**. More specifically, the data processing terminal **105** may in one embodiment be configured to receive data directly from the transmitter unit **102** via the communication link, where the communication link, as described above, may be configured for bi-directional communication.

In this embodiment, the data processing terminal **105** which may include an insulin pump, may be configured to receive the analyte signals from the transmitter unit **102**, and thus, incorporate the functions of the receiver **104** including data processing for managing the patient's insulin therapy and analyte monitoring. In one embodiment, the communication link **103** may include one or more of an RF communication protocol, an infrared communication protocol, a Bluetooth® enabled communication protocol, an 802.11x wireless communication protocol, or an equivalent wireless communication protocol which would allow secure, wireless communication of several units (for example, per HIPAA requirements) while avoiding potential data collision and interference.

FIG. **2** is a block diagram of the transmitter of the data monitoring and detection system shown in FIG. **1** in accordance with one embodiment of the present invention.

Referring to the Figure, the transmitter unit **102** in one embodiment includes an analog interface **201** configured to communicate with the sensor **101** (FIG. **1**), a user input **202**, and a temperature detection section **203**, each of which is operatively coupled to a transmitter processor **204** such as a central processing unit (CPU). As can be seen from FIG. **2**, there are provided four contacts, three of which are electrodes—work electrode (W), guard contact (G), reference electrode (R), and counter electrode (C), each operatively coupled to the analog interface **201** of the transmitter unit **102** for connection to the sensor **101** (FIG. **1**). In one embodiment, each of the work electrode (W), guard contact (G), reference electrode (R), and counter electrode (C) may be made using a conductive material that is either printed or etched, for example, such as carbon which may be printed, or metal foil (e.g., gold) which may be etched.

Further shown in FIG. **2** are a transmitter serial communication section **205** and an RF transmitter **206**, each of which is also operatively coupled to the transmitter processor **204**. Moreover, a power supply **207** such as a battery is also provided in the transmitter unit **102** to provide the necessary power for the transmitter unit **102**. Additionally, as can be seen from the Figure, clock **208** is provided to, among others, supply real time information to the transmitter processor **204**.

In one embodiment, a unidirectional input path is established from the sensor **101** (FIG. **1**) and/or manufacturing and testing equipment to the analog interface **201** of the transmitter unit **102**, while a unidirectional output is established from the output of the RF transmitter **206** of the transmitter unit **102** for transmission to the primary receiver unit **104**. In this manner, a data path is shown in FIG. **2** between the aforementioned unidirectional input and output via a dedicated link **209** from the analog interface **201** to serial communication section **205**, thereafter to the processor **204**, and then to the RF transmitter **206**. As such, in one embodiment, via the data path described above, the transmitter unit **102** is configured to transmit to the primary receiver unit **104** (FIG. **1**), via the communication link **103** (FIG. **1**), processed and encoded data signals received from the sensor **101** (FIG. **1**). Additionally, the unidirectional communication data path between the analog interface **201** and the RF transmitter **206** discussed above allows for the configuration of the transmitter unit **102** for operation upon completion of the manufacturing process as well as for direct communication for diagnostic and testing purposes.

As discussed above, the transmitter processor **204** is configured to transmit control signals to the various sections of the transmitter unit **102** during the operation of the transmitter unit **102**. In one embodiment, the transmitter processor **204** also includes a memory (not shown) for storing data such as the identification information for the transmitter unit **102**, as well as the data signals received from the sensor **101**. The stored information may be retrieved and processed for transmission to the primary receiver unit **104** under the control of the transmitter processor **204**. Furthermore, the power supply **207** may include a commercially available battery.

The transmitter unit **102** is also configured such that the power supply section **207** is capable of providing power to the transmitter for a minimum of about three months of continuous operation after having been stored for about eighteen months in a low-power (non-operating) mode. In one embodiment, this may be achieved by the transmitter processor **204** operating in low power modes in the non-operating state, for example, drawing no more than approximately 1 μA of current. Indeed, in one embodiment, the final step during the manufacturing process of the transmitter unit **102** may place the transmitter unit **102** in the lower power, non-operating state (i.e., post-manufacture sleep mode). In this manner, the shelf life of the transmitter unit **102** may be significantly improved. Moreover, as shown in FIG. **2**, while the power supply unit **207** is shown as coupled to the processor **204**, and as such, the processor **204** is configured to provide control of the power supply unit **207**, it should be noted that within the scope of the present invention, the power supply unit **207** is configured to provide the necessary power to each of the components of the transmitter unit **102** shown in FIG. **2**.

Referring back to FIG. **2**, the power supply section **207** of the transmitter unit **102** in one embodiment may include a rechargeable battery unit that may be recharged by a separate power supply recharging unit (for example, provided in the receiver unit **104**) so that the transmitter unit **102** may be powered for a longer period of usage time. Moreover, in one embodiment, the transmitter unit **102** may be configured without a battery in the power supply section **207**, in which case the transmitter unit **102** may be configured to receive power from an external power supply source (for example, a battery) as discussed in further detail below.

Referring yet again to FIG. **2**, the temperature detection section **203** of the transmitter unit **102** is configured to monitor the temperature of the skin near the sensor insertion site. The temperature reading is used to adjust the analyte readings obtained from the analog interface **201**. The RF transmitter **206** of the transmitter unit **102** may be configured for operation in the frequency band of 315 MHz to 322 MHz, for example, in the United States. Further, in one embodiment, the RF transmitter **206** is configured to modulate the carrier frequency by performing Frequency Shift Keying and Manchester encoding. In one embodiment, the data transmission rate is 19,200 symbols per second, with a minimum transmission range for communication with the primary receiver unit **104**.

Referring yet again to FIG. **2**, also shown is a leak detection circuit **214** coupled to the guard contact (G) and the processor **204** in the transmitter unit **102** of the data monitoring and management system **100**. The leak detection circuit **214** in accordance with one embodiment of the present invention may be configured to detect leakage current in the sensor **101** to determine whether the measured sensor data are corrupt or whether the measured data from the sensor **101** is accurate.

Additional detailed description of the continuous analyte monitoring system, its various components including the functional descriptions of the transmitter are provided in U.S. Pat. No. 6,175,752 issued Jan. 16, 2001 entitled "Analyte Monitoring Device and Methods of Use", and in application

Ser. No. 10/745,878 filed Dec. 26, 2003, now U.S. Pat. No. 7,811,231, entitled "Continuous Glucose Monitoring System and Methods of Use", each assigned to the Assignee of the present application.

FIG. **3** is a block diagram of the receiver/monitor unit of the data monitoring and management system shown in FIG. **1** in accordance with one embodiment of the present invention. Referring to FIG. **3**, the primary receiver unit **104** includes a blood glucose test strip interface **301**, an RF receiver **302**, an input **303**, a temperature detection section **304**, and a clock **305**, each of which is operatively coupled to a receiver processor **307**. As can be further seen from the Figure, the primary receiver unit **104** also includes a power supply **306** operatively coupled to a power conversion and monitoring section **308**. Further, the power conversion and monitoring section **308** is also coupled to the receiver processor **307**. Moreover, also shown are a receiver serial communication section **309**, and an output **310**, each operatively coupled to the receiver processor **307**.

In one embodiment, the test strip interface **301** includes a glucose level testing portion to receive a manual insertion of a glucose test strip, and thereby determine and display the glucose level of the test strip on the output **310** of the primary receiver unit **104**. This manual testing of glucose can be used to calibrate sensor **101**. The RF receiver **302** is configured to communicate, via the communication link **103** (FIG. **1**) with the RF transmitter **206** of the transmitter unit **102**, to receive encoded data signals from the transmitter unit **102** for, among others, signal mixing, demodulation, and other data processing. The input **303** of the primary receiver unit **104** is configured to allow the user to enter information into the primary receiver unit **104** as needed. In one aspect, the input **303** may include one or more keys of a keypad, a touch-sensitive screen, or a voice-activated input command unit. The temperature detection section **304** is configured to provide temperature information of the primary receiver unit **104** to the receiver processor **307**, while the clock **305** provides, among others, real time information to the receiver processor **307**.

Each of the various components of the primary receiver unit **104** shown in FIG. **3** is powered by the power supply **306** which, in one embodiment, includes a battery. Furthermore, the power conversion and monitoring section **308** is configured to monitor the power usage by the various components in the primary receiver unit **104** for effective power management and to alert the user, for example, in the event of power usage which renders the primary receiver unit **104** in sub-optimal operating conditions. An example of such sub-optimal operating condition may include, for example, operating the vibration output mode (as discussed below) for a period of time thus substantially draining the power supply **306** while the processor **307** (thus, the primary receiver unit **104**) is turned on. Moreover, the power conversion and monitoring section **308** may additionally be configured to include a reverse polarity protection circuit such as a field effect transistor (FET) configured as a battery activated switch.

The serial communication section **309** in the primary receiver unit **104** is configured to provide a bi-directional communication path from the testing and/or manufacturing equipment for, among others, initialization, testing, and configuration of the primary receiver unit **104**. Serial communication section **309** can also be used to upload data to a computer, such as time-stamped blood glucose data. The communication link with an external device (not shown) can be made, for example, by cable, infrared (IR) or RF link. The output **310** of the primary receiver unit **104** is configured to provide, among others, a graphical user interface (GUI) such as a liquid crystal display (LCD) for displaying information. Additionally, the output **310** may also include an integrated speaker for outputting audible signals as well as to provide vibration output as commonly found in handheld electronic devices, such as mobile telephones presently available. In a further embodiment, the primary receiver unit **104** also includes an electro-luminescent lamp configured to provide backlighting to the output **310** for output visual display in dark ambient surroundings.

Referring back to FIG. **3**, the primary receiver unit **104** in one embodiment may also include a storage section such as a programmable, non-volatile memory device as part of the processor **307**, or provided separately in the primary receiver unit **104**, operatively coupled to the processor **307**. The processor **307** is further configured to perform Manchester decoding as well as error detection and correction upon the encoded data signals received from the transmitter unit **102** via the communication link **103**.

FIG. **4** is a functional diagram of the overall signal processing for noise filtering and signal dropout compensation, while FIG. **5** shows a flowchart illustrating the overall signal processing for noise filtering and signal dropout compensation in accordance with one embodiment of the present invention. Referring to the Figures, in one embodiment, signals measured are received from, for example, the analyte sensor **101** (FIG. **1**) and are provided to the state observer **410** which in one embodiment may be configured to provide prior or past noise filtered estimate to a process input estimator **420**.

In one embodiment, the process input estimator **420** may be configured to generate a process input estimate based on the prior or past noise filtered estimate of the received or measured signal (**510**), which is then provided to the state observer **410**. In one aspect, and as described in further detail below in conjunction with FIG. **6**, the process input estimate at a predetermined time t may be based on past noise filtered estimate of the signal.

Thereafter, in one embodiment, the state observer **410** may be configured to generate a noise filtered estimate of the measured or received signal based on the current measured or received signal and the process input estimate (**520**) received from the process input estimator **420**. In one embodiment and as described in further detail below in conjunction with FIG. **7**, using the real time process input and sensor measurement signals, a noise filtered estimate of the signal at the latest time t may be determined.

In one aspect, this routine of generating the process input estimate based on the past noise filtered estimate of the received or measured signal, and generating the noise filtered estimate of the signal based on the current received or measured signal and the current determined or generated process input estimate may be repeated for each measurement signal received, for example, from the analyte sensor **101** (FIG. **1**). In this manner, in one aspect, the noise filtered signals corresponding to the measured or received sensor signals may be determined.

Referring back to FIGS. **4** and **5**, in one embodiment, with the noise filtered estimate, the presence of signal dropouts are detected based on, for example, the current and past noise filtered estimate of the received or measured signal (**530**). More specifically, in one embodiment, a dropout detector **430** may be configured to detect signal dropouts, and thereafter, detection of signal dropouts are provided to dropout compensator **440**. In one aspect, the dropout detector **430** may be configured to generate a signal or notification associated with the detection of a signal dropout (as shown in FIG. **4**). That is, in one embodiment and as described in further detail below in conjunction with FIG. **8**, the dropout detector **430** may be configured to detect or estimate the presence or absence of signal dropouts at the predetermined time.

In one embodiment, the dropout compensator **440** may be configured to generate an estimate of the noise filtered, dropout compensated signal (**540**) when the signal dropout is detected (for example, by the dropout detector **430**), by subtracting the estimate of the current dropout signal source from the present noise filtered estimate of the signal. In this manner, and as described in further detail below in conjunction with FIGS. **9**-**10**, in one embodiment of the present invention, the noise filtered signal dropout mitigated or compensated signal may be generated to improve accuracy of the measured or received signal from, for example, the analyte sensor **101** (FIG. **1**).

FIG. **6** is a flowchart illustrating the process input estimation in accordance with one embodiment of the present invention. Referring to FIG. **6**, a mean component of the process input estimate $u_m(t)$ based on past noise filtered estimate of the signal is generated (**610**). For example, in one embodiment, a series of five past noise-filtered estimate of the signal, $x_i(t-5)$, $x_i(t-4)$, $x_i(t-3)$, $x_i(t-2)$, $x_i(t-1)$, the mean component of the process input estimate at time t, $u_m(t)$ may be determined by taking the unweighted average of these signals as shown by the following relationship:

$$u_m(t) = \frac{x_i(t-5) + x_i(t-4) + x_i(t-3) + x_i(t-2) + x_i(t-1)}{5} \tag{1}$$

Alternatively, the mean component of the process input estimate at time t may be determined by taking the weighted average of these signals as shown by the following relationship:

$$u_m(t) = \frac{a_5 x_i(t-5) + a_4 x_i(t-4) + a_3 x_i(t-3) + a_2 x_i(t-2) + a_1 x_i(t-1)}{a_5 + a_4 + a_3 + a_2 + a_1} \tag{2}$$

where the determination of the constants a_1, a_2, a_3, a_4, a_5, may be obtained based on empirical or analytical analysis of the analyte monitoring system.

In yet another embodiment, the mean component of the process input estimate at time t based on recent past data may be determined using filtering techniques, such as, but not limited to FIR filters.

Referring to FIG. **6**, with the mean component of the process input estimate $u_m(t)$ based on past noise filtered estimate of the signal determined, the difference component of the process input estimate at any time t, $u_d(t)$, may be generated (**620**) by, for example, taking an averaged difference of a series of noise-filtered estimate of the signal from the recent past. In one aspect, an unweighted average of the last three past differences may be used in the following manner:

$$u_d(t) = \frac{(x_i(t-4) - x_i(t-3)) + (x_i(t-3) - x_i(t-2)) + (x_i(t-2) - x_i(t-1))}{3} \tag{3}$$

Within the scope of the present invention, other approaches such as the use of FIR filter to determine the proper number of recent past values of x_i as well as the weighting of each difference may be used.

Referring again to FIG. **6**, after determining the difference component of the process input estimate at any time t, $u_d(t)$, the difference gain at any time t, $K_d(t)$, is determined (**630**), for example, by using past noise-filtered estimate of the signal, x_i, and/or the derived signals from x_i. For example, in one embodiment, a band-limited rate $X_{i\_bandRate}$ and a band-limited acceleration $x_{i\_bandAcc}$, may be determined at any time t, based solely on recent past values of x_i. Using the knowledge of how the amount of u_d would contribute to the total process input u at any time t relates to these two variables $X_{i\_bandRate}$ and $X_{i\_bandAcc}$, a functional relationship may be determined to ascertain the value of the difference gain K_d at any time t.

Alternatively, a lookup table can be constructed that determines the value of the difference gain K_d given the values of $X_{i\_bandRate}$ and $X_{i\_bandAcc}$ as shown below:

$$K_d = \begin{cases} 2 & \text{if } (X_{i\_bandRate} > 0)\ \&\ (x_{i\_bandAcc} > 0) \\ 1 & \text{if } (x_{i\_bandRate} > 0)\ \&\ (x_{i\_bandAcc} \le 0) \\ 1 & \text{if } (x_{i\_bandRate} \le 0)\ \&\ (x_{i\_bandAcc} \le 0) \\ 0.5 & \text{if } (x_{i\_bandRate} \le 0)\ \&\ (x_{i\_bandAcc} > 0) \end{cases} \tag{4}$$

In one aspect, the difference gain K_d may be used to scale the contribution of the difference component of the process input estimate u_d in the value of the process input estimate at a given time. For example, a relatively larger value of the difference gain K_d may indicate a larger contribution of the difference component of the process input estimate u_d in the value of the process input estimate at the particular time, and so on. In this manner, in one aspect, the lookup table may show the relationship between factors such as the band-limited rate $X_{i\_bandRate}$ and the band-limited acceleration $x_{i\_bandAcc}$ upon how much the difference component of the process input estimate u_d should contribute to the process input estimate value.

Referring again to FIG. **6**, with the mean component of the process input estimate $u_m(t)$, the difference component of the process input estimate at any time t, $u_d(t)$, and the difference gain at any time t, $K_d(t)$, the scaled difference component $u_{ds}(t)$ of the process input estimate may be determined (**640**) by multiplying the difference component of the process input estimate at any time t, $u_d(t)$ by the difference gain at any time t, $K_d(t)$. Thereafter, the scaled difference component $u_{ds}(t)$ of the process input estimate may be added to the mean component of the process input estimate $u_m(t)$ to determine the current process input estimate value u(t) (**650**).

FIG. **7** is a flowchart illustrating the noise filtered estimation. Referring to FIG. **7**, with an estimate of process input signal at any time t, u(t), and based on the measured signals from the analyte sensor z(t), in addition to past estimates of the noise-filtered signal $x_i(t-1)$, $x_i(t-2)$, . . . , the state observer **410** (FIG. **4**) may be configured to determine the estimate of noise-filtered signal at any time t, $x_i(t)$. In one aspect, the state observer **410** (FIG. **4**) may be configured to reduce the contribution of noise without introducing excessive undesirable distortion based on the estimate of process input signal at any time t, u(t), and the measured signals from the sensor z(t).

FIG. **8** is a flowchart illustrating signal dropout detection in accordance with one embodiment of the present invention. Referring to FIG. **8**, a present "fast rate" estimate $x_{df}(t)$ is determined based on present and past noise-filtered estimate of the signal (**810**). For example, a difference signal $x_d(t)$ may be determined based on the following expression:

$$x_d(t) = x_i(t) - x_i(t-1) \tag{5}$$

Thereafter, a fast rate may be extracted from the difference signal $x_d(t)$ by performing high pass filtering on the difference signal $x_d(t)$. In one embodiment, a discrete-time realization of a first order high pass filter function may be used to determine the present "fast rate" estimate $x_{df}(t)$:

$$x_{df}(t)=a_{hpfD}x_{df}(t-1)+x_d(t)-x_d(t-1) \quad (6)$$

where the value of a_{hpfD}, or the structure of the high pass filter may be determined in accordance with the suitable design configurations, for example, a value between zero and one.

Referring back to FIG. **8**, after determining the "fast rate" estimate $x_{df}(t)$, a present "slow rate" estimate $x_{ds}(t)$ is determined based on present and past noise-filtered estimate of the signal (**820**). For example, in one embodiment, the slow rate estimate $x_{ds}(t)$ may be determined by passing the simple difference through a low-pass filter, or alternatively, by taking the difference between the simple difference and the fast difference signals as shown, for example, by the following expression:

$$x_{ds}(t)=x_d(t)-x_{df}(t) \quad (7)$$

After determining the slow rate estimate $x_{ds}(t)$, it is determined whether there is a beginning of a large negative spike in the fast rate estimate $x_{df}(t)$ (**830**). That is, referring to FIG. **8**, the start of a signal dropout state is determined which is correlated to a spike in the fast difference. The fast difference does not generate a spike larger than a predetermined value in response to signals generated in the absence of dropouts. For example, adjusted to the units of glucose concentration, this may correspond to a fast rate in excess of −3 mg/(dL min). Although a rate of −3 mg/(dL min) or faster may be ascertained, when band pass filtered, the fast rate estimate $x_{df}(t)$ determined above does not occur in this range unless a signal dropout occurs.

Referring back to FIG. **8**, if the beginning of a large negative spike in the fast rate estimate $x_{df}(t)$ is detected, then the elapsed time period from the initial occurrence of the large negative spike is monitored (**840**), for example, by triggering a timer or a counter so as to monitor the elapsed time since the most recent signal dropout occurrence predicted estimate. In this manner, a safety check mechanism may be provided to determine situations where a signal dropout that was anticipated to have started has lasted in an undesirably long period of dropout time period. That is, as the signal dropouts are generally intermittent in nature, it is expected that the dropout does not last beyond the order of one hour, for example, and more commonly, in the order of five to 30 minutes.

Thereafter, it is determined whether a predetermined allowable time period has elapsed (**850**). As shown in FIG. **8**, if it is determined the allowable time period has not elapsed, then the beginning or onset of the signal dropout is expected. On the other hand, if the predetermined allowable time period has elapsed, then the end of the signal dropout is expected. Referring again to FIG. **8**, when the beginning of a large negative spike in the fast rate estimate $x_{df}(t)$ is not detected, it is determined whether an end of a large positive spike (for example, in the order of +3 mg/(dL min)) in the fast rate estimate $x_{df}(t)$ is detected (**860**). If the end of the large positive spike in the fast rate estimate $x_{df}(t)$ is detected, then the end of the signal dropout is expected. On the other hand, if the end of the large positive spike in the fast rate estimate $x_{df}(t)$ is not detected, then no signal dropout is expected.

That is, a signal dropout is generally correlated to a large positive spike in the fast difference. Thus, in this case, the tail of the large positive spike is monitored and detected as the end of the signal dropout. In one embodiment, this maximizes the likelihood of detecting most of the instances within a signal dropout.

In this manner, in one embodiment of the present invention, the presence of signal dropout may be monitored and detected based on, for example, present and past noise filtered estimate of the signals.

FIG. **9** is a flowchart illustrating an overall signal dropout compensation in accordance with one embodiment of the present invention. Referring to FIG. **9**, a momentum-based estimate is determined based on the present slow difference and previous momentum-based estimate (**910**). That is, with the present and past noise filtered estimate of the signal, the present and past slow and fast rate estimates determined as described above, and with the signal dropout detection estimation determined above, the momentum-based estimate is determined based on the present slow difference and previous momentum-based estimate. That is, in one embodiment, a momentum-based estimate may factor in a signal without dropouts as being likely to project (e.g., extrapolate) based on its past signal and its prior trend.

Referring back to FIG. **9**, after determining the momentum based estimate using the present slow difference and prior momentum-based estimate, an averaged value of the present or current momentum-based estimate and the present noise filtered estimate is determined (**920**). Thereafter, an inertial gain based on the present and past slow rate estimate is determined (**930**), and which may be configured to scale the contribution of the momentum-based estimate determined using the present slow different and the previous momentum based estimate above in the final dropout compensated gain. Referring again to FIG. **9**, after determining the inertial gain, a tracking gain is determined based on the inertial gain (**940**). In one embodiment, the determined tracking gain may be configured to scale the impact of the determined average value of the present momentum-based estimate and the present noise-filtered estimate, in the determination of the final dropout compensated signal (**950**) as discussed below.

Referring to FIG. **9**, after determining the tracking gain, the dropout compensated signal is determined (**950**). In one embodiment, the dropout-compensated signal equals the noise-filtered estimate of the signal x_i, when no dropout is estimated. Otherwise, the dropout compensated signal may be a weighted average of the momentum-based estimate ($x_{momentum}$) as discussed above and the averaged momentum and noise-filtered estimate ($x_{average}$) also discussed above. In one aspect, the weighing factors for the weighted average of the momentum-based estimate ($x_{momentum}$) and the averaged momentum and noise-filtered estimate ($x_{average}$) may be the inertial gain $K_{inertial}$ and tracking gain $K_{tracking}$, respectively. For example, the dropout compensated signal at any time t, $x'_{dci}(t)$ in one embodiment may be determined in accordance with the following relationship:

$$x'_{dci}(t)=(K_{inertial}(t)x_{momentum}(t)+(K_{tracking}(t)x_{average}(t)) \quad (8)$$

In a further embodiment, the determination of the dropout compensated signal at any time t, $x'_{dci}(t)$ may be refined to ensure a smooth transition depending upon the underlying conditions, as described in further detail below in conjunction with FIG. **10**.

Referring back to FIG. **9**, after determining the dropout compensated signal, the dropout compensated signal may be clipped to be within a predetermined range (**960**), for example, such that the dropout compensated signal is not less than the noise-filtered signal, and further, that it is not greater than a specified safety ratio times the noise-filtered signal.

In certain cases, the resulting value of the dropout compensated signal $x'_{dci}(t)$ may fall below the noise-filtered estimate $x_i(t)$. Since by definition, a dropout is a phenomena that can only reduce the true value of a signal, the relationship (8) above for determining the dropout compensated signal may be modified by ensuring that its value never goes below $x_i(t)$ at any given time, and as shown by the following expression:

$$x_{dci}(t) = \begin{cases} x'_{dci}(t) & \text{for } x'_{dci}(t) \geq x_i(t) \\ x_i(t) & \text{for } x'_{dci}(t) < x_i(t) \end{cases} \quad (9)$$

FIG. **10** is flowchart illustrating a detailed signal dropout compensation determination of FIG. **9** in accordance with one embodiment of the present invention. Referring to FIG. **10**, for example, in determining the drop-compensated signal, it is first determined whether signal dropout is detected. If signal dropout is not detected, then it is determined whether a preset time period has elapsed since the end of the last dropout occurrence. If it is determined that a preset time period has elapsed, then the dropout compensated signal may be based upon the present noise filtered signal. In one aspect, the preset time period may be a predetermined time period that may be considered a long period of time. On the other hand, if it is determined that the preset time period has not elapsed (that is, the end of the occurrence of a signal dropout has recently occurred), then the dropout compensated signal may be based upon a smooth transition using the previous dropout compensated signal and the present noise filtered signal.

Indeed, referring to FIG. **10**, it can be seen that depending upon the determination of the timing of the signal dropout occurrence, in particular embodiments, the dropout compensated signal may be determined based on one or more factors as shown in the Figure and also described above.

Referring again to the Figures, in particular embodiments, the processings associated with the noise filtering, signal dropout detection estimation and compensation may be performed by one or more processing units of the one or more receiver unit (**104**, **106**), the transmitter unit **102** or the data processing terminal/infusion section **105**. In addition, the one or more of the transmitter unit **102**, the primary receiver unit **104**, secondary receiver unit **106**, or the data processing terminal/infusion section **105** may also incorporate a blood glucose meter functionality, such that, the housing of the respective one or more of the transmitter unit **102**, the primary receiver unit **104**, secondary receiver unit **106**, or the data processing terminal/infusion section **105** may include a test strip port configured to receive a blood sample for determining one or more blood glucose levels of the patient.

In a further embodiment, the one or more of the transmitter unit **102**, the primary receiver unit **104**, secondary receiver unit **106**, or the data processing terminal/infusion section **105** may be configured to receive the blood glucose value wirelessly over a communication link from, for example, a glucose meter. In still a further embodiment, the user or patient manipulating or using the analyte monitoring system **100** (FIG. **1**) may manually input the blood glucose value using, for example, a user interface (for example, a keyboard, keypad, and the like) incorporated in the one or more of the transmitter unit **102**, the primary receiver unit **104**, secondary receiver unit **106**, or the data processing terminal/infusion section **105**.

A method in one embodiment includes monitoring a data stream, generating a noise-filtered signal associated with the data stream, detecting a presence of a signal dropout based on the noise filtered signal, and estimating a noise filtered dropout compensated signal based on the noise filtered signal and the determination of the presence of the signal dropout.

In one aspect, generating the noise filtered signal may include generating one or more frequency-shaped signals based on the monitored data stream, and further, which may include high pass filtering the monitored data stream.

Also, generating the noise filtered signal in another aspect may be based on one or more previous noise filtered signals.

The method in a further embodiment may include outputting the noise filtered signal. The method in still another aspect may include outputting the noise filtered dropout compensated signal.

The method may also include generating a signal associated with detecting the presence of a signal dropout.

Moreover, the data stream in one embodiment may be associated with a monitored analyte level of a patient.

An apparatus in another embodiment includes one or more processors, and a memory for storing instructions which, when executed by the one or more processors, causes the one or more processors to monitor a data stream, generate a noise-filtered signal associated with the data stream, detect a presence of a signal dropout based on the noise filtered signal, and estimate a noise filtered dropout compensated signal based on the noise filtered signal and the determination of the presence of the signal dropout.

The memory may be further configured for storing instructions which, when executed by the one or more processors, causes the one or more processors to generate one or more frequency-shaped signals based on the monitored data stream.

In another aspect, the memory may be further configured for storing instructions which, when executed by the one or more processors, causes the one or more processors to generate the one or more frequency shaped signals by high pass filtering the monitored data stream.

In still another aspect, the memory may be further configured for storing instructions which, when executed by the one or more processors, causes the one or more processors to generate the noise filtered signal based on one or more previous noise filtered signals.

Moreover, the memory may be further configured for storing instructions which, when executed by the one or more processors, causes the one or more processors to output the noise filtered signal.

In yet another embodiment, the memory may be further configured for storing instructions which, when executed by the one or more processors, causes the one or more processors to output the noise filtered dropout compensated signal.

Additionally, the memory may be further configured for storing instructions which, when executed by the one or more processors, causes the one or more processors to generate a signal associated with detecting the presence of a signal dropout.

A system in accordance with still another embodiment may include an analyte sensor configured to monitor an analyte of a patient, a data processing section operatively coupled to the analyte sensor, the data processing section further including one or more processors, and a memory for storing instructions which, when executed by the one or more processors, causes the one or more processors to monitor a data stream, generate a noise-filtered signal associated with the data stream, detect a presence of a signal dropout based on the noise filtered signal, and estimate a noise filtered dropout compensated signal based on the noise filtered signal and the determination of the presence of the signal dropout.

The data processing section may include a data transmission unit operatively coupled to one or more processors configured to transmit the data stream. In another aspect, the data processing section may include a data receiving unit operatively coupled to the one or more processors and configured to receive the data stream.

The analyte sensor may include a glucose sensor.

Moreover, the memory may be further configured for storing instructions which, when executed by the one or more processors, causes the one or more processors to store one or more of the data stream, the noise filtered signal, or the noise filtered dropout compensated signal.

The various processes described above including the processes performed by the receiver unit **104/106** or transmitter unit **102** in the software application execution environment in the analyte monitoring system **100** including the processes and routines described in conjunction with FIGS. **5-10**, may be embodied as computer programs developed using an object oriented language that allows the modeling of complex systems with modular objects to create abstractions that are representative of real world, physical objects and their interrelationships. The software required to carry out the inventive process, which may be stored in the memory or storage unit of the receiver unit **104/106** or transmitter unit **102** may be developed by a person of ordinary skill in the art and may include one or more computer program products.

Various other modifications and alterations in the structure and method of operation of this invention will be apparent to those skilled in the art without departing from the scope and spirit of the invention. Although the invention has been described in connection with specific preferred embodiments, it should be understood that the invention as claimed should not be unduly limited to such specific embodiments. It is intended that the following claims define the scope of the present invention and that structures and methods within the scope of these claims and their equivalents be covered thereby.

What is claimed is:

1. A glucose monitoring system, comprising:

an in vivo glucose sensor;

sensor electronics that generates glucose data corresponding to a monitored glucose level based on signals received from the in vivo glucose sensor; and

a glucose data processing unit that determines noise filtered glucose data based on stored noise filtered estimates of the glucose data received from the sensor electronics, that identifies dropouts in the noise filtered glucose data over a predetermined time period, and that compensates for the identified dropouts in the noise filtered glucose data over the predetermined time period to increase accuracy of the generated glucose data, the glucose data processing unit further including an output unit to output information corresponding to the noise filtered glucose data over the predetermined time period.

2. The system of claim **1**, wherein the glucose data processing unit includes a filter that clips the dropout compensated noise filtered glucose signals to be within a predetermined range.

3. The system of claim **2**, wherein the clipped dropout compensated noise filtered glucose signals are not less than the noise filtered signals.

4. The system of claim **2**, wherein the clipped dropout compensated noise filtered glucose signals are not greater than a predetermined safety multiple of the noise filtered signals.

5. The system of claim **1**, wherein the glucose data processing unit identifies dropouts in the noise filtered glucose data over the predetermined time period based on a positive spike in the glucose data rate of change that exceeds a predetermined threshold.

6. The system of claim **1**, wherein the glucose data processing unit determines a fast rate estimate and a slow rate estimate based on the stored noise filtered estimates of the glucose data to identify dropouts in the noise filtered glucose data.

7. The system of claim **6**, wherein spikes in the fast rate estimate and the slow rate estimate are associated with dropouts in the noise filtered glucose data.

8. The system of claim **1**, wherein the glucose data processing unit includes an infusion device.

9. The system of claim **8**, wherein the infusion device determines a medication therapy profile based on the glucose data from the in vivo glucose sensor.

10. The system of claim **6**, wherein the glucose data processing unit includes a data computing device.

11. The system of claim **1**, wherein the sensor electronics communicates the generated glucose data to the glucose data processing unit over a wireless communication link.

12. The system of claim **1**, wherein the sensor electronics communicates the generated glucose data to the glucose data processing unit using Bluetooth communication protocol.

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